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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/938,940 | 08/24/2001 | J. Bryan Jones | GC525-C3 | 3800 |

5100 7590 07/25/2003

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

HUTSON, RICHARD G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,940

Applicant(s)

JONES ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17,20-23,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14-17,20-23,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants amendment of the specification and claims 14, and the cancellation of claims 18 and 19, Paper No. 10, 5/12/2003, is acknowledged. Applicants' arguments filed on 5/12/2003, Paper No. 13, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Claims 14-17, 20-23, 34 and 35 are still at issue and are present for examination.

Information Disclosure Statement

Applicants filing of information disclosure, Paper No. 11, filed 5/23/2003, is acknowledged. It is brought to applicants attention that each of the references listed on the newly supplied 1449 are identical to those listed on the previous 1449 as part of the information disclosure, Paper No. 3, 8/24/2001, a second copy of which is being supplied to applicants with this action.

Drawings

As stated in the previous office action, the drawings filed on 8/24/2001 are objected to for the reasons stated on the enclosed form PTO-948. Applicants statement regarding the filing of a supplemental amendment comprising corrections of formal drawings to follow shortly is acknowledged. **Note, applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17, 20-23, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applied to previous claims 14-23, 34 and 35. Applicants have cancelled claims 18 and 19 and amended claim 14 and traverse the rejection as it applies to the newly amended claims.

Newly amended claims 14-17, 20-23, 34 and 35 are directed to all possible chemically modified mutant enzymes with one or more amino acid residues replaced by a cysteine residue, wherein the one or more amino acids replaced by a cysteine are in a subsite of the enzyme, the subsite being selected from the group consisting of S1, S1' and S2 and wherein at least some of the cysteine residues are modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selected from the group consisting of: $-\text{SCH}_2(p\text{-CH}_3\text{-C}_6\text{H}_4)$, $-\text{SCH}_2(p\text{-OCH}_3\text{-C}_6\text{H}_4)$, $-\text{SCH}_2(p\text{-CF}_3\text{-C}_6\text{H}_4)$ and $-\text{SCH}_2(2,4\text{-diNO}_2\text{-C}_6\text{H}_3)$.

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Applicants traverse this rejection on the basis that the written description requirement is satisfied if the description clearly allows persons of ordinary skill in the art to recognize what has been invented (see e.g., MPEP 2163 et. Seq.). Applicants submit that applicants amendment such that the a cysteine is replaced in a subsite of the enzyme, the subsite being selected from the group consisting of S1, S1' and S2, has limited the sites for replacement such that the claimed genus is described with sufficient clarity to one of ordinary skill in the art and the claim therefore satisfies the written description requirement.

Applicants traversal is not found persuasive. Applicants amendment such that the claimed genus of chemically modified mutant enzymes must comprise a mutation such as a cysteine replacement in a subsite of the enzyme, the subsite being selected from the group consisting of S1, S1' and S2, while limiting the sites for cysteine replacement of the chemically modified mutant enzymes such that the modification of the claimed mutant enzyme is described with sufficient clarity to one of ordinary skill in the art, does not sufficiently describe the claimed genus that is drawn to any and all enzymes modified in such a manner. As previously stated, the specification only provides the representative species of a chemically modified mutant *Bacillus lentus* subtilisin wherein the chemical modification corresponds to the replacement of amino acid residues N62, L217 and S166, with a cysteine residue, wherein the cysteine residue is modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selected from the group consisting of: -SCH₂(*p*-CH₃-C₆H₄), -SCH₂(*p*-OCH₃-C₆H₄), -SCH₂(*p*-CF₃-C₆H₄) and -SCH₂(2,4-diNO₂-

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C₆H₃), encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these enzymes by any identifying structural characteristics or properties other than the activities recited for the disclosed species, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would not recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 14-17, 20-23, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chemically modified mutant *Bacillus lentus* subtilisin wherein the chemical modification corresponds to the replacement of amino acid residues N62, L217 and S166, with a cysteine residue, wherein the cysteine residue is modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selected from the group consisting of: -SCH₂(*p*-CH₃-C₆H₄), -SCH₂(*p*-OCH₃-C₆H₄), -SCH₂(*p*-CF₃-C₆H₄) and -SCH₂(2,4-diNO₂-C₆H₃), does not reasonably provide enablement for any chemically modified mutant enzyme with one or more amino acid residues replaced by a cysteine

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residue, wherein at least some of the cysteine residues are modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selected from the group consisting of: $-\text{SCH}_2(p\text{-CH}_3\text{-C}_6\text{H}_4)$, $-\text{SCH}_2(p\text{-OCH}_3\text{-C}_6\text{H}_4)$, $-\text{SCH}_2(p\text{-CF}_3\text{-C}_6\text{H}_4)$ and $-\text{SCH}_2(2,4\text{-diNO}_2\text{-C}_6\text{H}_3)$. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to previous claims 14-23, 34 and 35. Applicants have cancelled claims 18 and 19 and amended claim 14 and traverse the rejection as it applies to the newly amended claims.

Applicants submit that a claim is enabled if the disclosure, when filed, contains sufficient information to allow one of ordinary skill in the art to make and/or the claimed invention. As in the above argument pertaining to the lack of written description rejection, applicants submit that applicants amendment such that the a cysteine is replaced in a subsite of the enzyme, the subsite being selected from the group consisting of S1, S1' and S2, has limited the sites for replacement and this in combination with the disclosure provides sufficient information for one of ordinary skill in the art to make and/or use the claimed invention for the full scope of the claim and thus claim 14 as well as those claims which depend from claim 14 are enabled.

Applicants traversal is not found persuasive. As discussed above, applicants amendment such that the claimed genus of chemically modified mutant enzymes must comprise a mutation such as a cysteine replacement in a subsite of the enzyme, the subsite being selected from the group consisting of S1, S1' and S2, while limiting the

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sites for cysteine replacement of the chemically modified mutant enzymes such that the modification of the claimed mutant enzyme is described with sufficient clarity to one of ordinary skill in the art, does not sufficiently enable the scope of the claimed genus of chemically modified mutant enzymes which comprises any and all enzymes modified in such a manner.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make **and** use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any of the claimed chemically modified mutant enzymes having any activity or function. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 16 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6,284,512 B1. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 15, 17, 20-23, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 9 and 10 of U.S. Patent No. 6,284,512 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8, 9 and 10 of U.S. Patent No. 6,284,512 B1 anticipate claims 14, 15, 17-23, 34 and 35, respectively. Applicants statement regarding the filing of a supplemental amendment comprising a terminal disclaimer to follow shortly is acknowledged.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal stroke extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
July 24, 2003